UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. XAVIER BECERRA, Secretary, United States Department of Health and Human Services, Defendant.	)	Civil Action No. 17-2645 (ABJ)

MEMORANDUM OPINION

In this case, plaintiff American Clinical Laboratory Association challenged a regulation issued by the Secretary of the U.S. Department of Health and Human Services[1] governing the reporting of the pricing information used to set Medicare reimbursement rates for clinical diagnostic laboratory services. Plaintiff is a trade association that represents clinical and anatomic pathology laboratories, Compl. [Dkt. # 1] ¶ 18, and the challenged regulation implements section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), which established a new scheme for setting Medicare reimbursement rates for these laboratory tests.

The parties have filed cross-motions for summary judgement and for the reasons set forth below, the Court will dismiss this case as moot.

1 The newly appointed Secretary, Xavier Becerra, has been substituted as defendant pursuant to Federal Rule of Civil Procedure 25(d).

BACKGROUND

Clinical diagnostic laboratory tests are tests performed on specimens of bodily fluids or tissue that are used to monitor, diagnose, and treat patients, and they range from routine blood tests to sophisticated genetic and molecular tests. Compl. ¶ 1. The federal Medicare program, which is administered by the Department of Health and Human Services ("HHS" or "the Department") and pays for healthcare for elderly and disabled individuals, is the nation's largest purchaser of clinical laboratory services. *See* 42 U.S.C. § 1395 *et seq*.; *Am. Clinical Lab'y Ass'n. v. Azar*, 931 F.3d 1195, 1199 (2019).

How Medicare reimburses laboratories for clinical diagnostic laboratory tests depends on the setting in which they are provided. These services may be provided in hospitals on an inpatient or outpatient basis, in nursing facilities, or at a doctor's office. Compl. ¶ 22. If a Medicare beneficiary receives these laboratory tests at a hospital, Medicare pays for *all* of the services the hospital provides to the beneficiary – medications, room and board, laboratory, and all other services – in one bundled payment pursuant to either the Inpatient Prospective Payment System ("IPPS") or the Outpatient Prospective Payment System ("OPPS"). *See* 42 U.S.C. §§ 1395ww(d), 1395l(t); *Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1051, 1053 (D.C. Cir. 1997) (explaining that the IPPS provides a single payment "in full satisfaction of the bundle of covered items and services provided during a single inpatient hospital stay" based on the diagnosis related group ("DRG") of the patient's stay, rather than on the separate services a patient received from the hospital). In contrast, if a beneficiary receives laboratory tests outside of a hospital setting, such as at a doctor's office or from an independent laboratory, Medicare pays the laboratory for each test performed based on the Clinical Laboratory Fee Schedule ("CLFS") or the

Physician Fee Schedule ("PFS").[2] *See* 81 Fed. Reg. 41,036, 41,038 (June 23, 2016); J.A. [Dkt. # 38].[3]

Some hospital laboratories provide services not only to hospital patients, but also externally, to individuals who are not patients of the hospital. For example, the blood sample taken at a doctor's office may be sent to a hospital laboratory for analysis. Such hospital laboratory services provided to non-hospital patients are referred to as "outreach services," and Medicare pays for them as it would for an independent laboratory: on a fee-for-service basis based on the CLFS or the PFS. *Id.*, citing 42 U.S.C. §§ 1832, 1833(a), (b), (h), 1861.

I. Protecting Access to Medicare Act of 2014

In 2014, Congress passed the Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, 128 Stat. 1040, to overhaul Medicare payments for laboratory services. Before PAMA, Medicare's fee schedule for clinical laboratory services was set by the Secretary based on a "regional, statewide, or carrier service area basis," with adjustments for differences in wages. 42 U.S.C. § 1395*l*(h)(1)(B)–(C), (h)(4)(A). In 2013, the Department's Office of Inspector General found that Medicare was paying eighteen to thirty percent more for laboratory tests than private insurers were paying. *Am. Clinical Lab'y Ass'n*, 931 F.3d at 1199. Congress passed PAMA in an effort to make Medicare's reimbursement rates comparable to those paid by private insurers for the same laboratory tests. *Id.*; *see also* 160 Cong. Rec. S2860 (May 8, 2014) (stating Congress sought to "ensure that Medicare rates reflect true market rates for laboratory services").

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2 Generally speaking, tests that require both a professional and technical component to provide the test results are paid under the PFS, and those that require no interpretation by a physician or professional are paid under the CLFS. *See* 42 C.F.R. § 414.40(b)(2).

3 Citations to the Joint Appendix refer to the Bates numbers appearing at the bottom right of each page of the appendix.

PAMA established a market-based approach for setting payment rates based on the amounts private payors pay for these tests. *See* 42 U.S.C. § 1395m-1. Section 216 of PAMA requires "applicable laborator[ies]" to report to the Department every three years the amounts and volume of payments they receive from private insurers, 42 U.S.C. § 1395m-1(a),[4] exempting certain "low volume or low expenditure" laboratories from the requirement. *Id.* § 1395m-1(a)(2). It requires the Secretary to compile the reported data to calculate Medicare's reimbursement rates for laboratory tests. *Id.* § 1395m-1(b) (requiring the Secretary to calculate a weighted median for each laboratory test "by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory").

PAMA defines "applicable laboratory" to mean "a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues are from this section, section 1395l(h) of this title, or section 1395w–4 of this title." *Id.* § 1395m-1(a)(2). In other words, a laboratory must receive the majority of its Medicare revenues from the CLFS or the PFS – the payment mechanisms covering non-hospital settings – rather than the inpatient or outpatient payment mechanisms, to be obligated to report its private payor data to the Secretary. *Id.*

II. Rulemaking and Litigation History

As required by the statute, the Secretary promulgated a rule in June of 2016 to implement PAMA's provisions, including its data collection requirements. *See* 42 U.S.C. § 1395m-1(a)(12); 81 Fed. Reg. 41,036 (June 23, 2016); J.A. at 0001, 0004–17 ("2016 Rule"). The 2016 Rule included its own definition for "applicable laboratory": a laboratory that "bills Medicare Part B under its own NPI." 81 Fed. Reg. at 41,047. The NPI, or National Provider Number, is a unique

4 In the case of advanced diagnostic laboratory tests, laboratories must report this information annually. 42 U.S.C. § 1395m-1(a).

billing number assigned by the Department to health care providers to use when submitting claims for Medicare reimbursement. 81 Fed. Reg. at 41,042, citing 45 C.F.R. § 162.406 (2004); 80 Fed. Reg. 59,386, 59,392 (Oct. 1, 2015); J.A. at 00075.

Plaintiff filed this lawsuit on December 11, 2017, challenging the Secretary's regulatory definition of "applicable laboratory." Compl. [Dkt. #1] ¶¶ 3–4. According to plaintiff, defining the term to mean only laboratories that bill Medicare under their own NPIs excluded significant numbers of hospital laboratories that provide outreach services from the Secretary's data collection; this is because most hospital laboratories bill under their hospitals' NPIs, rather than their own. *See id.* ¶ 44 (alleging the Secretary improperly "treated the entire hospital as a laboratory for purposes of evaluating whether the statutory revenue requirements are satisfied" and "effectively carved out hospital laboratories from the statutory requirements," ensuring the reporting obligations would be imposed primarily on only independent and physician-office laboratories). At the end of the day, less than one percent "of the total number of laboratories that currently serve Medicare beneficiaries" reported data to the Secretary in 2016. *Id.* ¶ 7.

The Court did not reach the merits of plaintiff's claim that this narrowing of the definition was arbitrary and capricious. A motion to dismiss was filed, and in light of a provision Congress included in PAMA, the Court concluded that judicial review was precluded, and it dismissed the case for lack of subject matter jurisdiction. Order (Sept. 21, 2018) [Dkt. # 46]; Mem. Op. [Dkt. # 47]. Plaintiff appealed the ruling. Notice of Appeal [Dkt. # 48].

Two months later, on November 23, 2018, the Secretary promulgated another rule that amended the definition of "applicable laboratory" to address the problem plaintiff had identified. 83 Fed. Reg. 59,452 (Nov. 23, 2018) ("2018 Rule"). The 2018 Rule revised the definition to add "hospital outreach laboratories" that "bill[ ] Medicare Part B on the CMS 1450 under bill type 14x," a claim form used by hospitals for non-patient laboratory services. *Id.* at 60,074; *see also*

Am. Clinical Lab. Ass'n, 931 F.3d at 1202 (explaining that "the CMS-1450 14x TOB" is "a billing form used only by hospital outreach laboratories").

On July 30, 2019, the D.C. Circuit overturned the dismissal of the case, remanding the matter to the Court "to address in the first instance the merits of petitioner's arbitrary-and-capricious challenge." *Am. Clinical Lab'y Ass'n*, 931 F.3d at 1209.

After remand, plaintiff filed a motion for summary judgement on October 14, 2019. Pl.'s Mot. for Summ. J. [Dkt. # 53] ("Pl.'s Mot."). Defendant filed a cross-motion for summary judgment and opposition on November 22, 2019. Def.'s Cross-Mot. and Opp. to Pl.'s Mot. for Summ. J. [Dkt. # 54]; Def.'s Mem. in Supp. [Dkt. # 54-1] ("Def.'s Mem."). Plaintiff filed its cross-opposition and reply brief on December 13, 2019, Pl.'s Reply in Supp. of Pl.'s Mot. and Opp. to Def.'s Cross-Mot. [Dkt. # 56] ("Pl.'s Opp. & Reply"), and defendant filed his reply brief on January 24, 2020. Def.'s Reply in Supp. of Cross-Mot. for Summ. J. [Dkt. # 59].

STANDARD OF REVIEW

I. Subject Matter Jurisdiction

Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *see also Gen. Motors Corp. v. EPA*, 363 F.3d 442, 448 (D.C. Cir. 2004) ("As a court of limited jurisdiction, we begin, and end, with an examination of our jurisdiction."). "[B]ecause subject-matter jurisdiction is 'an Art[icle] III as well as a statutory requirement . . . no action of the parties can confer subject-matter jurisdiction upon a federal court.'" *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003), quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982). "Federal courts cannot address the merits of a case until jurisdiction – the power to decide – is established." *Hancock v. Urban Outfitters, Inc.*, 830 F.3d 511, 513 (D.C. Cir. 2016).

II. Summary Judgment

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The party seeking summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) (internal quotation marks omitted). To defeat summary judgment, the non-moving party must "designate specific facts showing that there is a genuine issue for trial." *Id.* at 324 (internal quotation marks omitted).

The mere existence of a factual dispute is insufficient to preclude summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). A dispute is "genuine" only if a reasonable fact-finder could find for the non-moving party; a fact is "material" only if it is capable of affecting the outcome of the litigation. *Id.* at 248; *see also Laningham v. U.S. Navy*, 813 F.2d 1236, 1241 (D.C. Cir. 1987). In assessing a party's motion, the court must "view the facts and draw reasonable inferences 'in the light most favorable to the party opposing the summary judgment motion.'" *Scott v. Harris*, 550 U.S. 372, 378 (2007) (alterations omitted), quoting *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962) (per curiam).

"The rule governing cross-motions for summary judgment . . . is that neither party waives the right to a full trial on the merits by filing its own motion; each side concedes that no material facts are at issue only for the purposes of its own motion." *Sherwood v. Wash. Post*, 871 F.2d 1144, 1147 n.4 (D.C. Cir. 1989) (alteration in original), quoting *McKenzie v. Sawyer*, 684 F.2d 62, 68 n.3 (D.C. Cir. 1982). In assessing each party's motion, "[a]ll underlying facts and inferences

are analyzed in the light most favorable to the non-moving party." *N.S. ex rel. Stein v. District of Columbia*, 709 F. Supp. 2d 57, 65 (D.D.C. 2010), citing *Anderson*, 477 U.S. at 247.

ANALYSIS

Plaintiff challenged the definition of "applicable laboratory" in the 2016 Rule, asserting that it was detrimental to plaintiff's members because it excluded many hospital laboratories from reporting their pricing data to the Department, and that therefore, its promulgation violated the Administrative Procedure Act ("APA") and PAMA. *See* Compl.; Pl.'s Mot. In addition to defending the 2016 Rule on the merits, defendant raises several jurisdictional and procedural challenges to the complaint, arguing that plaintiff lacks standing, that plaintiff failed to present its claims and exhaust its remedies with the agency, and that the matter is moot because of the 2018 Rule. *See* Def.'s Mem. Because the absence of a live controversy divests this Court of jurisdiction to decide the lawsuit even if plaintiff's APA claim has force, the Court must stop here.

A case becomes moot "when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." *Larsen v. U.S. Navy*, 525 F.3d 1, 3–4 (D.C. Cir. 2008), quoting *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979); *see also Honig v. Doe*, 484 U.S. 305, 317 (1988) (explaining that Article III, Section 2 of the Constitution permits federal courts to adjudicate only "actual, ongoing controversies"). If events outrun the controversy such that the Court can grant no meaningful relief, the case must be dismissed as moot. *See, e.g.*, *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992); *McBryde v. Comm. to Review,* 264 F.3d 52, 55 (D.C. Cir. 2001). "Even where litigation poses a live controversy when filed, the [mootness] doctrine requires a federal court to refrain from deciding it if 'events have so transpired that [a judicial] decision will neither presently affect the parties' rights nor have a more-than-speculative chance of affecting them in the future.'" *Clarke v. United States*, 915 F.2d 699, 701 (D.C. Cir. 1990), quoting *Transwestern Pipeline Co. v. FERC*, 897 F.2d 570, 575 (D.C. Cir.

1990); *see also Spencer v. Kemna*, 523 U.S. 1, 18 (1998) (noting that a case is moot when "there is nothing for [the court] to remedy, even if [it] were disposed to do so").

"A plaintiff always bears the ultimate burden of showing . . . that a court has jurisdiction over his claims." *Han Jeong Seon v. Lynch*, 223 F. Supp. 3d 95, 103 (D.D.C. 2016), citing *Delta Air Lines v. Exp.-Imp. Bank of United States*, 85 F. Supp. 3d 250, 259 (D.D.C. 2015); *see also Muhammad v. FDIC*, 751 F. Supp. 2d 114, 118 (D.D.C. 2010) ("Plaintiff [must establish] by a preponderance of the evidence that the Court possesses jurisdiction."). But where mootness is at issue, "[t]he initial 'heavy burden' of establishing mootness lies with the party asserting a case is moot, [and] the opposing party bears the burden of showing an exception applies." *Han*, 223 F. Supp. 3d at 103 (second alteration added), quoting *Honeywell Int'l, Inc. v. Nuclear Regul. Comm'n*, 628 F.3d 568, 576 (D.C. Cir. 2010). "[M]ootness, however it may have come about, simply deprives [the court] of [its] power to act." *Id.*, quoting *Spencer*, 523 U.S. at 18 (first alteration added).

Defendant argues that plaintiff's claims concerning the 2016 Rule are moot because the Secretary revised the definition of "applicable laboratory" in the 2018 Rule, and the challenged definition is no longer applicable. Def.'s Mem. at 22–24. This lawsuit does not challenge the new rule, so the only remedy that would be available to plaintiff here would be retrospective relief for any past payments that were calculated using the only 2016 Rule – that is, payments calculated for 2018–20 based on data collected data in early 2017 using the challenged definition. *Id.* at 23. At first blush, that would appear to create a live controversy. But defendant argues that the Court cannot provide plaintiff or its members any relief as to the payment calculations for 2018–20 because the statute bars judicial review of "the establishment of payment amounts" under PAMA. *Id.* at 23–24, citing 42 U.S.C. § 1395m-1(h).

Plaintiff, on the other hand, emphasizes that its complaint does not directly challenge the determination of the 2018–20 payment amounts. Pl.'s Opp. & Reply at 17–18. It challenges the "unlawful reporting rule" used to determine which laboratories would report data to the Secretary. *Id.* at 17. Plaintiff emphasizes that the D.C. Circuit recognized the "bifurcated structure" of PAMA, which divided the statute into the data collection process and the establishment of payment amounts. *Am. Clinical Lab'y Ass'n*, 931 F.3d at 1207. Although the results of the data collection process are used to establish Medicare payment amounts, the data collection provision is distinct from its rate-estimation provisions. *Id.* Plaintiff contends that its inability to challenge the reimbursement rates themselves does not prevent the Court from requiring the Secretary to comply with the data collection provision, even if this "necessarily result[s] in a change to the rates." Pl.'s Opp. & Reply at 17.

Plaintiff asserts if the Court were to rule in its favor, nothing in the statute would prevent the Court from ordering the Secretary to collect 2017 data using a regulation that complies with PAMA and then recalculate payment rates for 2018–20. Pl.'s Opp. & Reply at 17 (arguing "those rates can change *without* any challenge to their 'establishment'") (emphasis in original). New data could be collected. But PAMA provides that "payment amounts under this section shall not be subject to *any* adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment)." 42 U.S.C. § 1395m-1(b)(4)(B) (emphasis added). So even if the Court were to rule in plaintiff's favor on the merits, it could not order the agency to revise any payment amounts in the fee schedules used to determine 2018–20 payments or any particular payments to plaintiff's members. *See Keli v. Rice*, 571 F. Supp. 2d 127, 132 (D.D.C. 2008) (ruling that case was moot where "the language of the statute unequivocally bars the Court from granting the relief sought").

Further, the Court could not vacate the challenged definition and order the Secretary to bring his regulations into compliance with the Medicare statute since the definition is no longer in effect. In other words, any decision "will neither presently affect the parties' rights nor have a more-than-speculative chance of affecting them in the future." *Clarke*, 915 F.2d at 701 (internal quotation marks omitted). For these reasons, the Court finds that this dispute is moot.

CONCLUSION

For the reasons set for above, the Court will dismiss the case for lack of subject matter jurisdiction.

AMY BERMAN JACKSON
United States District Judge

DATE: March 30, 2021